In the Matter of

PATRICIA L. CLARKE, M.D.

Holder of License No. 26877

In the State of Arizona.

For the Practice of Allopathic Medicine

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Case No. MD-07-0690A

MD-07-0546A MD-07-0689A MD-07-0565A

MD-07-0503A MD-07-0534A MD-06-0911A MD-06-0800A

MD-07-0304A

CONSENT AGREEMENT FOR DECREE OF CENSURE AND PROBATION

# **CONSENT AGREEMENT**

By mutual agreement and understanding, between the Arizona Medical Board ("Board") and Patricia L. Clarke, M.D. ("Respondent"), the parties agreed to the following disposition of this matter.

- Respondent has read and understands this Consent Agreement and the stipulated Findings of Fact, Conclusions of Law and Order ("Consent Agreement").
   Respondent acknowledges that she has the right to consult with legal counsel regarding this matter.
- 2. By entering into this Consent Agreement, Respondent voluntarily relinquishes any rights to a hearing or judicial review in state or federal court on the matters alleged, or to challenge this Consent Agreement in its entirety as issued by the Board, and waives any other cause of action related thereto or arising from said Consent Agreement.
- This Consent Agreement is not effective until approved by the Board and signed by its Executive Director.

- 4. The Board may adopt this Consent Agreement or any part thereof. This Consent Agreement, or any part thereof, may be considered in any future disciplinary action against Respondent.
- 5. This Consent Agreement does not constitute a dismissal or resolution of other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding. The acceptance of this Consent Agreement does not preclude any other agency, subdivision or officer of this State from instituting other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.
- 6. All admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, said admissions by Respondent are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, civil or criminal court proceeding, in the State of Arizona or any other state or federal court.
- 7. Upon signing this agreement, and returning this document (or a copy thereof) to the Board's Executive Director, Respondent may not revoke the acceptance of the Consent Agreement. Respondent may not make any modifications to the document. Any modifications to this original document are ineffective and void unless mutually approved by the parties.
- 8. If the Board does not adopt this Consent Agreement, Respondent will not assert as a defense that the Board's consideration of this Consent Agreement constitutes bias, prejudice, prejudgment or other similar defense.

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- 9. This Consent Agreement, once approved and signed, is a public record that will be publicly disseminated as a formal action of the Board and will be reported to the National Practitioner Data Bank and to the Arizona Medical Board's website.
- 10. If any part of the Consent Agreement is later declared void or otherwise unenforceable, the remainder of the Consent Agreement in its entirety shall remain in force and effect.
- 11. Any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. § § 32-1401(27)(r) ("[v]/olating a formal order, probation, consent agreement or stipulation issued or entered into by the board or its executive director under this chapter") and 32-1451.
  - 12. Respondent has read and understands the condition(s) of probation.

PATRICIA L. CLARKE, M.D.

DATED: 2/20/2008

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# FINDINGS OF FACT

- The Board is the duly constituted authority for the regulation and control of the practice of allopathic medicine in the State of Arizona.
- Respondent is the holder of license number 26877 for the practice of allopathic medicine in the State of Arizona.
- 3. The Board initiated case number MD-07-0690A, MD-07-0546A, MD-07-0689A, MD-07-0565A, MD-07-0534A, MD-06-0911A and MD-06-0800A after receiving complaints regarding Respondent's care and treatment of multiple patients.

# MD-07-0690A - PATIENT RW

- 4. On August 25, 2006, a sixty-one year-old male patient ("RW") presented to Respondent for primary care with a history of gastroesophageal reflux disease (GERD) and complaints of shortness of breath, cough and fatigue. Respondent obtained pertussis panels, which revealed a negative immunoglobulin (Ig) M and positive IgG and IgA. Respondent consulted a specialist and obtained Centers for Disease Control (CDC) guidelines for confirming a diagnosis of pertussis. Respondent did not perform the CDC recommended tests or provide any treatment to RW.
- 5. During a follow up visit on August 30, 2006, RW reported flu-like symptoms and possible exposure at work. Respondent reviewed the pertussis panel from August 25, 2006 and noted under the review of symptoms that RW had shortness of breath (SOB), fatigue and fever. Respondent treated RW with Biaxin for pertussis IgA+ for two weeks. There was no clear documentation in the record whether Respondent was treating RW's pertussis based on history of exposure or Ig testing.
- At the follow up visit RW also reported his cough had improved.
  Respondent ordered laboratory tests, including a non-fasting glucose, which was reported

as 124. Respondent diagnosed RW with diabetes based on the laboratory test and office accucheck values.

- 7. On September 19, 2006, Respondent ordered additional non-fasting glucose testing, which was reported as 131. From September 20, 2006 to December 18, 2006, Respondent saw RW numerous times, counseled him for diabetes and anxiety and recommended RW obtain a glucometer. RW also attended education sessions for diabetes. RW eventually saw another primary care provider where he was retested and was told that he did not have diabetes.
- 8. The standard of care requires a physician to diagnose and treat diabetes based on two fasting blood glucose laboratory values that are greater than or equal to 126.
- 9. Respondent deviated from the standard of care because she did not did not obtain two fasting blood glucose laboratory values from RW that were greater than or equal to 126. Respondent diagnosed RW with diabetes based on non-fasting laboratory values and recommended treatment based on office accucheck values.
- 10. The standard of care requires a physician diagnosing pertussis to obtain a nasopharyngeal swab or aspirate from the posterior nasopharynx in all patients with suspected pertussis. Isolation of Bordetella pertussis from the clinical specimen confirms the diagnosis.
- 11. Respondent deviated from the standard of care because she did not obtain a nasopharyngeal swab or aspirate from the posterior nasopharynx in RW, a patient suspected of pertussis.
- 12. The standard of care requires a physician to treat active pertussis or give post-exposure prophylaxis with an appropriate macrolide agent with the recommended course of treatment of Clarithromycin (Biaxin) 500mg twice a day for seven days.

- 13. Respondent deviated from the standard of care because she did not appropriately treat RW. Respondent treated RW with Biaxin for two weeks, which is a significantly longer course than recommended.
- 14. Respondent's inappropriate course of antibiotic treatment for RW, with a history of GERD, could have worsened his symptoms and caused additional gastrointestinal side effects. Respondent's misinforming RW with a diagnosis of diabetes could have contributed to RW's anxiety. RW's multiple visits to Respondent for diabetes were excessive and could have contributed to increased cost. RW attended education sessions for diabetes that were unnecessary.
- 15. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because they were unclear as to whether she was treating RW for pertussis based on history of exposure or by diagnosis.

# **MD-07-0546A - PATIENT RM**

16. Respondent saw a twenty-four year-old female patient ("RM") on several occasions. After RM's initial visit on February 8, 2007, Respondent ordered laboratories including a fasting glucose, which was reported as 111 (normal reference range is 65-99). Respondent obtained two additional non-fasting glucose values at follow up visits, which were reported as 114 and 109. Respondent wrote RM a prescription for a glucometer kit and signed documentation certifying that the glucometer was medically necessary even

though RM did not meet diagnostic criteria for diabetes. Respondent instructed RM document her fasting and non-fasting glucose values.

- 17. On March 16, 2007, during a follow up visit, RM reported fasting glucose ranges of 90-140 and non-fasting ranges of 97-132. Respondent reviewed the values and diagnosed RM with diabetes. Respondent treated RM with diet, exercise and nutritional supplements. RM eventually sought treatment with another provider who diagnosed her with metabolic syndrome.
- 18. The standard of care requires a physician to obtain two fasting plasma glucose values greater than 126 for the diagnosis of diabetes.
- 19. Respondent deviated from the standard of care because she did not obtain two fasting plasma glucose values for RM's diagnosis of diabetes.
- 20. RM was misinformed about the diagnosis of diabetes and was treated with nutritional supplements that were not proven effective in the peer-reviewed literature. RM was harmed because she underwent excessive, extensive and repeated laboratory testing.
- 21. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because she documented that a glucometer was medically necessary for RM.

# <u>MD-07-0689A - PATIENT SW</u>

22. From August 2006 to December 2006, a sixty-three year-old female patient ("SW") presented to Respondent on numerous occasions for primary care.

Respondent's medical record documentation was illegible and she used non-standard abbreviations during several of these visits.

- 23. On August 15, 2006, SW presented complaining of a barking cough, fever and symptoms of bacterial urinary tract infection (UTI). Respondent prescribed Biaxin for the UTI even though Biaxin does not cover common gram negative pathogens of the urinary tract. Respondent also ordered pertussis lg testing and a complete blood count, which showed persistent mild anemia. Respondent referred SW for a hematology consultation for the anemia. SW eventually sought care with other providers.
- 24. In response to the Board's investigation, Respondent stated she prescribed Biaxin for lower respiratory infection. However, this is not supported by documentation in SW's record. Although Ig testing was done to evaluate for pertussis exposure due to SW's complaints of a barking cough, the records show Respondent was not treating SW for pertussis when the antibiotic was prescribed.
- 25. When a patient presents with an elevated temperature and symptoms of bacterial UTI, the standard of care requires a physician to begin an appropriate antibiotic treatment.
- 26. Respondent deviated from the standard of care because she did not appropriately treat SW for possible bacterial UTI.
- 27. Respondent's inappropriate treatment could have resulted in a worsened infection and bacteremia.
- 28. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of

treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because her documentation was illegible and she used non-standard abbreviations.

### MD-07-0565A - PATIENT CH

- 29. On May 7, 2007, a fifty-three year-old female patient ("CH") presented for an initial visit with Respondent with a history of depression and back pain. During the appointment Respondent reported a medical diagnosis for CH that belonged to a different patient with a similar name. Respondent apologized for not properly identifying CH prior to discussing a medical diagnosis that was not her diagnosis and continued with the new patient interview. Respondent did not document this mistake in CH's medical record. Respondent referred CH for laboratory tests, including pelvic and lumbar spine x-rays. The pelvic x-ray showed an osteochondroma and the spine x-ray showed degenerative changes. Respondent did not notify CH of the abnormal x-ray findings.
- 30. During an investigational interview with Board staff, Respondent admitted to the mistaken identification made at the initial patient visit on May 7, 2007 and that she did not notify CH of the abnormal x-ray findings.
- 31. The standard of care requires a physician to properly identify a patient prior to discussing a medical diagnosis.
- 32. Respondent deviated from the standard of care because she did not identify CH prior to discussing a medical diagnosis that was not her diagnosis.
- 33. The standard of care requires a physician to notify a patient about an abnormal x-ray finding and arrange appropriate follow up.
- 34. Respondent deviated from the standard of care because she did not notify CH of the abnormal x-ray findings and she did not arrange appropriate follow up care.
- 35. Respondent's failure to notify CH of an osteochondroma could have led to continued growth and malignant transformation.

36. Respondent's failure to provide timely laboratory results could have caused a delay in identifying, clarifying or initiating management change in a specific medical condition. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because she did not document not properly identifying CH prior to discussing a medical diagnosis that was not CH's diagnosis.

### MD-07-0534A - PATIENT JA

- 37. From December 15, 2005 to June 28, 2007, a fifty-two year-old female patient ("JA") presented to Respondent on numerous occasions for primary care. At several of these visits Respondent's medical record documentation was illegible and difficult to follow.
- 38. On December 22, 2005, Respondent evaluated JA and ordered laboratory tests, including blood glucose levels that showed an elevated fasting glucose level of 124 and a normal capillary (fingerstick) blood sugar level. Respondent discussed these results with JA during the follow up visit on January 11, 2006 and diagnosed her with glucose change.
- 39. From April 6, 2006 to December 20, 2006, Respondent saw JA on numerous visits and diagnosed her with diabetes based on capillary blood testing. Respondent also provided JA with diabetic education at these visits.
- 40. The standard of care requires a physician to diagnose diabetes after establishing two elevated fasting glucose values per venipuncture.

- 41. Respondent deviated from the standard of care because she did not establish two elevated fasting glucose values per venipuncture.
- 42. Respondent's failure to provide timely laboratory results could have caused a delay in identifying, clarifying or initiating management change in a specific medical condition.
- 43. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because her documentation was illegible and difficult to follow.

# MD-06-0911A - PATIENT ED

- 44. A thirty-six year-old female patient ("ED") presented to Respondent on five occasions for office visits for various issues and complaints. At several of these visits Respondent's medical record documentation was illegible and she used non-standard abbreviations.
- 45. On May 11, 2006, ED presented to Respondent for an annual Pap smear examination. On May 30, 2006, ED returned to discuss her results with Respondent; however, the complete results were not available. Following that visit, ED contacted Respondent's office on several occasions in July 2006 for a complete copy of the results. However, ED did not receive the results until she was informed by Respondent's office staff on August 4, 2006, that she could come in and pick them up. On that same date, when ED arrived to pick up the results, she was told that Respondent would like to see her and discuss the results. ED eventually sought care with another physician.

- 46. The standard of care requires a physician to provide the patient with their laboratory results upon request in a timely manner.
- 47. Respondent deviated from the standard of care because she did not provide ED with her laboratory results upon request in a timely manner.
- A8. Respondent's failure to provide timely laboratory results could have caused a delay in identifying, clarifying or initiating management change in a specific medical condition. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because her documentation was illegible and she used non-standard abbreviations.

# MD-06-0800A - PATIENT JW

- 49. On November 23, 2005 and November 28, 2005, a twenty-seven year-old female patient ("JW") presented for a well woman examination and follow up appointment, respectively. Respondent's medical record documentation was illegible and she used non-standard abbreviations.
- 50. JW's chief complaint on November 23, 2005, was a history of amenorrhea and dyspareunia. Respondent ordered blood test and diagnosed JW with amenorrhea and dyspareunia. Respondent did not document a differential diagnosis; perform a genitourinary or pelvic examination or order a thyrotropin study to determine the cause of JW's complaint of amenorrhea. Respondent billed a 99205 Evaluation and Management code for the visit, which requires a comprehensive history and examination and to make a medical decision of high complexity. This code does not correspond with JW's medical

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records. Specifically, Respondent did not explore the possible etiology of JW's abnormal menses or dyspareunia; she did not document a history of present illnesses and she did not perform an examination, which would allow her to make a medical decision of high complexity.

- 51. On November 28, 2005, JW returned complaining of fatigue and amenorrhea. Respondent ordered a urinalysis and obtained a pulse oximetry reading. Respondent performed a physical examination; however, she did not perform a genitourinary or pelvic examination. Following the visit, Respondent's office staff made two subsequent attempts to reschedule JW for a genitourinary and pelvic examination, but JW did not return.
- 52. During the Board's interview, Board staff obtained JW's medical record. JW's laboratory tests were not included in her record. During an investigational interview with Board staff on November 1, 2006, Respondent stated that in her practice, the laboratory results remain on the computer and are not downloaded or reviewed until the patient is seen during a followup appointment. Because JW did not return after the November 28, 2005 visit, her laboratory results were never downloaded from the computer, were never reviewed and were therefore, not part of her patient chart.
- 53. When a patient presents complaining of a history of amenorrhea and dyspareunia, the standard of care requires a physician to perform a physical examination, which includes a genitourinary and pelvic examination and to order a thyrotropin study.
- 54. Respondent deviated from the standard of care because she did not perform a genitourinary and pelvic examination and she did not order a thyrotropin study.
- 55. Respondent's failure to evaluate JW's complaint could have caused a delay in proper diagnosis and treatment of her amenorrhea and dyspareunia.

Respondent's failure to provide timely laboratory results could have caused a delay in identifying, clarifying or initiating management change in a specific medical condition.

56. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because she did not document a differential diagnosis and documentation was illegible and she used non-standard abbreviations.

## <u>MD-07-0304A – PATIENT RB</u>

- 57. The Board initiated case number MD-07-0304A after receiving a complaint from a physician ("Physician") alleging Respondent failed to provide medical records for a seven year-old female patient ("RB") following a written request by Child Protective Services ("CPS").
- 58. Physician was court appointed to examine RB after CPS intervened regarding possible neglect. CPS provided Respondent with several written requests beginning February 20, 2007 to provide RB's medical records to Physician. Respondent never provided a copy of RB's medical records to Physician.
- 59. In response to the Board's investigation, Respondent's records of RB were reviewed. Respondent's documentation was illegible and she used non-standard abbreviations.
- 60. On December 4, 2006, RB presented to Respondent as a new patient for gastrointestinal complaints and nutritional issues. Respondent ordered laboratory tests

and made dietary recommendations. However, she did not obtain a baseline height and weight on RB.

- 61. When a new patient presents with nutritional or gastrointestinal problems, the standard of care requires a physician to obtain baseline height and weight.
- 62. Respondent deviated from the standard of care because she did not obtain a baseline height and weight of RB at her initial office visit.
- 63. Respondent's failure to record RB's baseline height and weight could have led to inadequate assessments of status changes, which could have caused a delay in proper treatment and conflicting advice on diet and repeated laboratory testing.
- 64. A physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. A.R.S. § 32-1401(2). Respondent's records were inadequate because her documentation was illegible and she used non-standard abbreviations.

### **CONCLUSIONS OF LAW**

- The Board possesses jurisdiction over the subject matter hereof and over Respondent.
- 2. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(27)(e) ("[f]ailing or refusing to maintain adequate records on a patient."), A.R.S. § 32-1401(27)(q) ("[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public."), A.R.S. § 32-1401(27)(u) ("[c]harging a fee for services not rendered or dividing a professional fee for patient referrals among health care institutions or between these providers and institutions

or a contractual arrangement that has the same effect.") and A.R.S. § 32-1401(27)(rr) ("[f]ailing to make patient medical records in the physician's possession promptly available to a physician assistant, a nurse practitioner, a person licensed pursuant to this chapter or a podiatrist, chiropractor, naturopathic physician, osteopathic physician or homeopathic physician licensed under chapter 7, 8, 14, 17 or 29 of this title on receipt of proper authorization to do so from the patient, a minor patient's parent, the patient's legal guardian or the patient's authorized representative or failing to comply with title 12, chapter 13, article 7.1.").

#### ORDER

#### IT IS HEREBY ORDERED THAT:

- 1. Respondent is issued a Decree of Censure for failure to appropriately diagnose and treat diabetes and pertussis in a patient; for inappropriately diagnosing two patients with diabetes; for documenting that a glucometer was medically necessary for a patient who did not have diabetes; for inappropriately prescribing Biaxin for a possible urinary tract infection; for failure to properly identify a patient prior to discussing a medical diagnosis; for failure to notify a patient regarding an abnormal x-ray result; for failure to provide complete pap smear results upon patient's request in a timely manner; for inappropriate billing; for failure to perform and order appropriate laboratory testing for amenorrhea; for failure to obtain baseline height and weight in a child with nutritional deficiency and for failure to maintain adequate medical records.
- Respondent is placed on probation for five years with the following terms and conditions:

# A. <u>Physician Assessment and Clinical Education Program (PACE)</u>

Respondent shall undergo an evaluation within 60 days with PACE at the University of California, San Diego, at Respondent's expense. Any and all reports,

assessments or other documents generated by PACE shall be forwarded by PACE to the Board for review. The Board retains jurisdiction and may initiate new action based upon the results of the PACE evaluation.

## B. Chart Review

Board Staff or its agents shall conduct bi-monthly chart reviews. Based upon the chart review, the Board retains jurisdiction to take additional disciplinary or remedial action.

### C. Obey All Laws

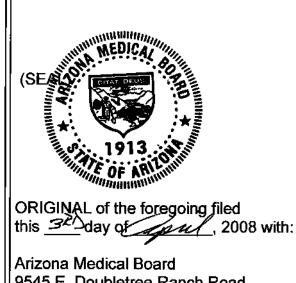
Respondent shall obey all state, federal and local laws, all rules governing the practice of medicine in Arizona, and remain in full compliance with any court order criminal probation, payments and other orders.

## D. <u>Tolling</u>

In the event Respondent should leave Arizona to reside or practice outside the State or for any reason should Respondent stop practicing medicine in Arizona, Respondent shall notify the Executive Director in writing within ten days of departure and return or the dates of non-practice within Arizona. Non-practice is defined as any period of time exceeding thirty days during which Respondent is not engaging in the practice of medicine. Periods of temporary or permanent residence or practice outside Arizona or of non-practice within Arizona, will not apply to the reduction of the probationary period.

3. This Order is the final disposition of case number MD-07-0690A, MD-07-0546A, MD-07-0689A, MD-07-0565A, MD-07-0534A, MD-06-0911A, MD-06-0800A and MD-07-0304A.

DATED AND EFFECTIVE this 5<sup>cd</sup> day of 10cd , 2008.



#### ARIZONA MEDICAL BOARD

Bv **Executive Director** 

ORIGINAL of the foregoing filed

9545 E. Doubletree Ranch Road Scottsdale, AZ 85258

EXECUTED COPY of the foregoing mailed this 3 day of \_\_\_\_\_\_, 2008 to:

Stephen Myers Myers & Jenkins PC 3003 North Central Avenue, Suite 1900 Phoenix, AZ 85012-2910

EXECUTED COPY of the foregoing mailed this 300 day of \_\_\_\_\_, 2008 to:

Patricia L. Clarke, M.D. Address of Record

Investigational Review